

REMARKS

Applicant intends this response to be a complete response to the Examiner's 31 November 2005 Final Office Action. Applicant has labeled the paragraphs in his response to correspond to the paragraph labeling in the Office Action for the convenience of the Examiner.

DETAILED ACTION

1. The amendment filed August 28, 2006, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 1-43 are pending.
3. In the reply filed on May 18, 2005, applicant elected of Group II, claims 8-13 and 29-42 (now including claim 43), *Allium cepa* for species A and rhinovirus for species B **without** traverse.
4. Claims 1-7, 11, 14-38, 41, and 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 18, 2005.
5. Claims 8-10, 12, 13, 39-40 and 43 are examined on the merits solely in regards to the elected species.

Claim Rejections - 35 USC § 112

6. **Claims 8-10, 12, 13, 39-40 and 43** stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The Examiner contends as follows:

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended claim 8 to state that the viral infection is treated with a composition comprising greater than 95% of the particulate material from *Allium cepa*. However, applicant's specification does not support the use of a composition comprising the specific percentage of *Allium cepa*. The specification discusses a percentage of greater than 95% in regards to the particle sizes being between 1 to 1,4000 microns. Specifically, the specification states "Preferably, the utilize procedure for particulating the processed dehydrated *Allium*, preferably *Allium cepa*, material will result in most (greater than 95%) of the particles or granules in the resultant composition having an average size ranging from 1 to 1,400 microns...(see page 11, lines 5-8)." The specification does not support including the *A. cepa* in the pharmaceutical composition at amounts greater than 95% only that the particle distribution is at least 95% between 1 to 1,400 microns. Thus, the addition of the limitation requiring 95% of *A. cepa* in the pharmaceutical composition does not have support in the specification as originally filed. The specification does discuss specific dosage of *A. cepa* to administer, but does not state the percentage of *A. cepa* in these dosages.

Applicants understand the Examiner's understanding of the 95% and agree with the Examiner's reading and have amended the claims to remove this reference.

Claim Rejections - 35 USC § 103

7. **Claims 8-10 and 12** stand rejected under 35 U.S.C. 103(a) as being unpatentable over Derwent English abstract of Chinese Pat. Appl. No. 1089152 A (1994) for the reasons set forth in the previous Office action.

The Examiner contends as follows:

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach using onion in the amounts claimed by applicant. However, the reference teaches only specifically mentions onion as one active ingredient in the method to treat the common cold. The reference does not specifically teach the percentage of onion included in the compositions. However, the dosage of a specific ingredient is well known in the art to be a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount dosage of onion to use in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of dosage amount would have been obvious at the time of applicant's invention.

Applicants disagree with the Examiner's reliance on Chinese Pat. Appl. No. 1089152 A (1994). The Derwent abstract is not complete and not in agreement with the abstract published by the EPO on espacenet (copy of espacenet display attached). The abstract for Chinese Pat. Appl. No. 1089152 A (1994) on espacenet reads as follows:

Onion product series in the form of tablet, instant granules, capsule, powder, emulsion, etc. includes food, beverage, health-care medicine and new drug, which are made up by adding Chinese herbal medicines, vegetables and food in pure onion product obtained by means of squeeze, organic solvent extraction and distillation. It may be used to cure hyperlipemia, hypercholesterol, arteriosclerosis, hypertension, arthritis, common cold, dysentery, rabies, diabetes, and baldness.

Applicants point out that in the espacenet version of the abstract, the composition of Chinese Pat. Appl. No. 1089152 A (1994) is prepared by means of squeeze, organic solvent extraction and distillation. Thus, the Chinese Pat. Appl. No. 1089152 A (1994) composition is on a composition "comprising a particulate, dehydrated plant material derived from a species of *Allium* selected from

the group consisting of *Allium cepa*, *Allium ampeloprasum*, *Allium fistulosa*, and *Allium schoenoprasum* having particles ranging in size from about 1 to 1,400 microns and having a water content of less than or equal to 5.5%" as set forth in independent claim 8. In fact, there is no suggestion in Chinese Pat. Appl. No. 1089152 A (1994) to a particulate, dehydrated plant material at all. Chinese Pat. Appl. No. 1089152 A (1994) is directed solely at an extracted and distilled product, even though the final product can be a powder – the composition does not comprise a particulate, dehydrated plant material. Thus, Chinese Pat. Appl. No. 1089152 A (1994) does not disclose, teach or suggestion a method administering a composition comprising a particulate, dehydrated plant material as is true in the present claims.

Because Chinese Pat. Appl. No. 1089152 A (1994) does not disclose, teach or even suggest a method of administering a particulate, dehydrated plant material composition, but only a method of administering an extracted and distilled composition irrespective of its final form, Chinese Pat. Appl. No. 1089152 A (1994) does render the pending claims of this invention obvious. Applicants, therefore, respectfully request withdrawal of this section 103(a) rejection.

8. **Claims 8-10, 12, 13, 39-40 and 43** stand rejected under 35 U.S.C. 103(a) as being unpatentable over Derwent English abstract of Chinese Pat. Appl. No. 1089152 A (1994) in view of US Pat. No. 4,409,237 for the reasons set forth in the previous Office action.

The Examiner contends as follows:

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that CN '152 teaches away from using a high dosage of onion in the composition based on the "significant amount" of other material included in the composition of CN '152. However, CN '152 is not considered by the examiner to require a "significant amount" of material other than the onion. The reference teaches only one active ingredient, onion, and states that this can be administered in various pharmaceutical forms. No other ingredients are specifically required. Thus, CN '152 is not considered to teach away from using a high dosage of onion. Therefore, the claims are considered properly rejected for the reasons of record.

Applicants repeat their arguments relating to Chinese Pat. Appl. No. 1089152 A (1994) as set forth above. While US Pat. No. 4,409,237 relates to powders and humidity and Chinese Pat. Appl. No. 1089152 A (1994) can be in the form of a powder, Chinese Pat. Appl. No. 1089152 A (1994) is not a method of administering a composition comprising a particulate, dehydrated plant material as is true in the present claims. The combination of Chinese Pat. Appl. No. 1089152 A (1994) and US Pat. No. 4,409,237 does nothing to remove the deficiencies of Chinese Pat. Appl. No.

1089152 A (1994) as it relates to the nature of the composition being administered, a composition derived from squeezing, solvent extracting and distilling – not a composition comprising a particulate, dehydrated plant material.

Because the combination of Chinese Pat. Appl. No. 1089152 A (1994) and US Pat. No. 4,409,237 does not disclose, teach or even suggest a method of administering a particulate, dehydrated plant material composition, but only a method of administering a powdered composition obtained by means of squeezing, solvent extracting and distilling, the combination does render the pending claims of this invention obvious. Applicants, therefore, respectfully request withdrawal of this section 103(a) rejection.

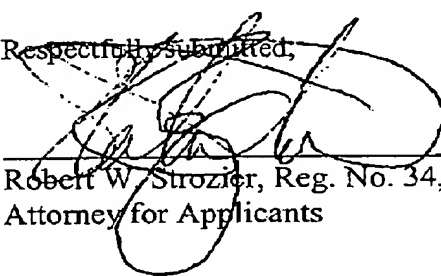
Having fully responded to the Examiner's Final Office Action, Applicants respectfully strongly urge that this application be passed onto allowance.

If it would be of assistance in resolving any issues in this application, the Examiner is kindly invited to contact applicant's attorney Robert W. Strozier at 713.977.7000.

The Commissioner is authorized to debit any underpayment or credit any overpayment to Deposit Account 501518.

Respectfully submitted,

Date: February 13, 2007


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Development for pure and compound onion products series

Publication number: CN1089152
Publication date: 1994-07-13
Inventor: RUMING GUO (CN); YING LIU (CN); BEIRONG GUO (CN)
Applicant: GUO RUMING (CN)
Classification:
- International: A61K9/00; A61K9/00; (IPC1-7): A61K35/78; A61K9/00
- European:
Application numbers: CN19931000513 19930101
Priority number(s): CN19931000513 19930101

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Abstract of CN1089152

Onion product series in the form of tablet, instant granules, capsule, powder, emulsion, etc. includes food, beverage, health-care medicine and new drug, which are made up by adding Chinese herbal medicines, vegetables and food in pure onion product obtained by means of squeeze, organic solvent extraction and distillation. It may be used to cure hyperlipemia, hypercholesterl, arteriosclerosis, hypertension, arthritis, common cold, dysentery, rabies, diabetes, and baldness.

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